

STATE OF VERMONT
AGENCY OF HUMAN SERVICES
Department of Vermont Health Access (DVHA)

SUBJECT: 340B Pricing Program – State Plan Amendment (SPA) 10-011

Public Comments received as of October 20, 2010:

On behalf of over 500 public and private non-profit hospitals enrolled in the 340B federal drug discount program, Safety Net Hospitals for Pharmaceutical Access (SNHPA) respectfully submits this letter in response to the request for comments regarding State Plan Amendment 10-011 (SPA 10-011). With this comment, SNHPA seeks to ensure that hospitals are able to retain and use their 340B savings to provide, improve, and expand services to disadvantaged populations, as Congress intended when it created the program nearly two decades ago. Accordingly, SNHPA strongly opposes SPA 10-011 which essentially would require 340B covered entities to give all their 340B savings to Vermont's Medicaid program.

SNHPA is an organization of hospitals that participate in the 340B program, including hospitals based in Vermont, other northern New England states, and throughout the country. Our mission is to increase the affordability and accessibility of pharmaceutical care for the nation's low-income and underserved populations. SNHPA monitors, educates, and serves as an advocate on legislative and regulatory issues related to drug pricing and other pharmacy matters affecting public and private non-profit hospitals and health systems that serve a large volume of uninsured and underinsured patients.

SNHPA strongly believes that 340B savings rightfully belong to 340B hospitals, not state Medicaid programs. When Congress created the 340B program, it clearly and unambiguously stated that the purpose of the program is "to enable [providers] to stretch, scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."¹ There is no indication in the legislative history that the program was intended to reduce Medicaid costs.

In addition to undermining the very purpose of the 340B program, SP 10-011 would place major financial and administrative burdens on 340B hospitals. Requiring providers to bill Medicaid at Actual Acquisition Cost (AAC) results in woefully inadequate reimbursement. While we applaud Vermont's proposal to pay an enhanced dispensing fee of \$10.20, this fee would only help offset the loss of 340B savings for drugs dispensed by hospital outpatient pharmacies. It would not be sufficient with respect to drugs dispensed or administered as part of a hospital outpatient encounter. Hospital clinic drugs often require special preparation because they are injected, infused, implanted, or inhaled. Adequate payment for these non-retail pharmacy services can exceed \$100 depending on the drug involved and the services required.

Moreover, most hospitals do not have the technical capability to bill Medicaid at a different rate than other payers for their non-retail drugs, and developing that capability would require a substantial economic investment. The Technical Specifications Document that accompanies SPA 10-011 states that hospital and retail pharmacies will be required to bill 340B eligible drugs at acquisition costs, rather than simply be reimbursed at acquisition costs. This requirement will create enormous operational complications for hospitals. Most hospitals have one chargemaster to establish charges for all hospital services, and the chargemaster does not include different charges for different payers. Having to create a separate chargemaster for 340B eligible Vermont Medicaid bills, or separate prices within its chargemaster for these charges, is simply

¹ H.R. Rep. No. 102-384, pt. II, at 12 (1992).

unworkable. The Department of Vermont Health Access (DVHA) is taking the benefit of the 340B program discounts but imposing all of the burden associated with that benefit on 340B providers.

Given the likely exorbitant cost of implementation, SP 10-011 could cause hospitals to incur a net loss on their 340B drugs billed to Medicaid at a time when providers are facing higher uncompensated care costs.

Lastly and most importantly, SP 10-011 would severely hamper 340B hospitals' ability to treat the uninsured, the underinsured, and Vermont's own Medicaid beneficiaries. This problem would be exacerbated as the number of Medicaid enrollees increases under health care reform. The Patient Protection and Affordable Care Act relies heavily upon Medicaid to expand insurance coverage. Medicaid already has reimbursement rates that are lower than most private payers. In the case of 340B drugs, this reimbursement gap is worsened further if providers are mandated to bill at AAC. Such a low reimbursement rate does not come close to covering the costs of comprehensive pharmacy services, including drug preparation, counseling, and administrative overhead. The Medicaid reimbursement gap poses a significant financial challenge to 340B providers since they treat a disproportionate share of Medicaid beneficiaries. The challenge will only grow as the hospitals begin to serve a majority of the newly eligible Medicaid enrollees under health care reform. The number of Medicaid enrollees will likely increase further as more employers decide not to offer health insurance to their employees due to the quickly rising cost of health care. Faced with this reality, safety net providers will continue to be dependent on reduced drug costs to offset the losses incurred in treating the uninsured, the underinsured, and the Medicaid population.

The following are the comments of Mary Hitchcock Memorial Hospital (MHMH) regarding Vermont State Plan Amendment (SPA) 10-011 proposed by the Department of Vermont Health Access (DVHA). As background, MHMH is located in Lebanon, New Hampshire and currently has 353 inpatient beds in operation. It serves a significant number of Medicaid patients, including Vermont Medicaid patients. MHMH qualifies for the 340B program as a rural referral center and, therefore, is not eligible to purchase orphan drugs with 340B discounts.¹ MHMH enrolled in the 340B program in September 2010, but has not yet begun purchasing drugs with 340B discounts.

MHMH opposes SPA 10-011 for the reasons set forth below.

SPA 10-011 is contrary to the purpose of the 340B program. SPA 10-011 essentially requires that all of a covered entity's 340B savings to be given to the Medicaid program. The 340B program discounts, however, are not intended to be passed to the Medicaid program or other government payers. The Health Resources and Services Administration (HRSA), which administers the 340B program, has stated:

HRSA agrees that the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities. Covered entities are the intended beneficiaries of the 340B program discounts, therefore, not State Medicaid programs. DVHA should not attempt to usurp the savings that are due to safety net providers through the 340B program.

Significantly, several years ago, HRSA required covered entities to pass their 340B discounts to Medicaid by billing at acquisition cost.³ In March 2000, HRSA retreated from this requirement and advised covered entities that it was reevaluating the issue.⁴ HRSA also clarified in March 2000 the right of covered entities to purchase their Medicaid drugs outside the 340B program, often referred to as the Medicaid carve-out option.⁵ By reimbursing for 340B eligible drugs at acquisition costs, SPA 10-011 has the effect of reinstating HRSA's former policy and forcing covered entities to "carve-in" for Medicaid, which is contrary to HRSA guidance.

SPA 10-011 will create significant administrative burdens for covered entities. The Technical Specifications Document that accompanies SPA 10-011 states that hospital and retail pharmacies will be required to bill 340B eligible drugs at acquisition costs, rather than simply be reimbursed at acquisition costs. This

requirement will create enormous operational complications for MHMH. MHMH, like most hospitals, has one chargemaster to establish charges for all hospital services and the chargemaster does not include different charges for different payers. Having to create a separate chargemaster for 340B eligible Vermont Medicaid bills, or separate prices within its chargemaster for these charges, is simply unworkable. DVHA is taking the benefit of the 340B program discounts, but imposing all of the burden associated with that benefit on 340B hospitals.

In addition, it would be impossible for any hospital to implement these changes effective October 1. SPA 10-011 was announced at the end of September, making it entirely unrealistic for a hospital to implement these changes by October 1.

SPA 10-011 is a significant change to billing and reimbursement rules for hospital outpatient drugs. The SPA 10-011 Technical Specifications Document states that hospital outpatient pharmacies must bill, and DVHA will reimburse for, 340B eligible drugs at acquisition cost, and that "[t]his is in accordance with current outpatient reimbursement methodology." In addition, the SPA does not modify the provisions governing payment to hospital outpatient pharmacies (it changes only those governing payment to retail pharmacies), indicating that DVHA is operating under the understanding that billing and reimbursement for hospital outpatient pharmacies will not change under the SPA. Hospital outpatient pharmacies do not bill DVHA at their acquisition costs and they are currently reimbursed at the national median APC rates, not acquisition costs.⁶ Therefore, SPA 10-011 is a significant deviation from the current billing and reimbursement rules for hospital outpatient drugs.

SPA 10-011 fails to address issues related to new covered entities. As stated above, MHMH is eligible for the 340B program as a rural referral center and, therefore, is not eligible to purchase orphan drugs with 340B program discounts. One other category of 340B hospital, however, is permitted to purchase orphan drugs with 340B program discounts. In addition, while MHMH recently enrolled with the 340B program, it has not begun to make purchases with 340B discounts.

It isn't clear how DVHA will distinguish orphan drugs purchased by 340B hospitals that are eligible to use discounts and those that are not. We assume that it is not DVHA's intent to enforce SPA 10-011 against hospitals that are enrolled in 340B but have not implemented the 340B program.

The 340B dispensing fee for compounded prescriptions is inadequate. SPA 10-011 implements a 340B dispensing fee of \$10.20 that applies to both Vermont pharmacies and out-of-state pharmacies and to both compounded prescriptions and all other prescriptions. While MHMH supports payment of the same dispensing fee to both Vermont and out-of-state pharmacies, the \$10.20 dispensing fee is grossly inadequate for compounded prescriptions, which require a significant amount of effort and time to fill. DVHA should raise the dispensing fee for compounded prescriptions to at least \$19.75, which is the current fee paid to Vermont retail pharmacies for compounded prescriptions.

¹ 42 U.S.C. § 256b(a)(4)(0), (e). Sole community hospitals also cannot buy orphan drugs with 340B discounts. *Id.* at § 256b(e).

² 75 Fed. Reg. 10,277 (March 5, 2010).

³ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 68,922, 68,923 (Dec. 29, 1993).

⁴ 65 Fed. Reg. 13,984(2000).

⁵ *Id.*

I am writing this letter in opposition to the current recommendation by DVHA to implement the 340B Drug Pricing Program (SPA 10-011) in the state of Vermont.

I feel that if this Program is implemented that it will have a very negative effect on all Pharmacies operating in the state of Vermont. There are additional costs related to Inventory management and replenishment associated with a 340B program that must be considered. The cost of the dispensing fee analysis was done 4 years ago and

is out of date. Additionally I feel that a profit component must be added to the dispensing fee if Pharmacies are to be in business.

I have previous experience with stores participating in 340B programs and I strongly feel that \$10.20 dispensing fee is not a fair amount to even cover the labor costs associated with filling these prescriptions.

Any consideration to reject this Amendment would be greatly appreciated and I look forward to hearing back from you on this critical matter that would have a very negative impact on Pharmacies in the State of Vermont.

I am writing this letter in opposition to the current recommendation by DVHA to implement the 340B Drug Pricing Program (SPA 10-011) in the state of Vermont.

I feel that if this Program is implemented that it will have a very negative effect on all Pharmacies operating in the state of Vermont. There are additional costs related to Inventory management and replenishment associated with a 340B program that must be considered. The cost of the dispensing fee analysis was done 4 years ago and is out of date. Additionally I feel that a profit component must be added to the dispensing fee if Pharmacies are to be in business.

I have previous experience with stores participating in 340B programs and I strongly feel that \$10.20 dispensing fee is not a fair amount to even cover the labor costs associated with filling these prescriptions.

I am also the current President of VACDS and I am sure that my colleagues would agree.

Any consideration to reject this Amendment would be greatly appreciated and I look forward to hearing back from you on this critical matter that would have a very negative impact on Pharmacies in the State of Vermont.

I am concerned on a few fronts – first, that we will be required to build a separate chargemaster for Vermont Medicaid patients so we can bill at the 340b cost. This would be an administrative nightmare for us. I have always been told that the law states we must bill everyone the same – the discounts taken are what differentiates the payors, and that is the responsibility of the payor to apply the discount, not the hospital.

To set up Vermont Medicaid with a different CHARGE structure could start a chain reaction which would significantly increase the cost to supply care to our patients. It's already difficult enough to bill every payor according to their specific rules. We have separate software systems to handle these back end billing issues. But this is beyond the capabilities of that software. You're basically asking us to create two sets of books – I'm sure you can understand the difficulty that would lie in that. We try to run a tight ship here and keep our costs down; this would require our hiring additional staff to comply with your request.

In addition, as a Critical Access Hospital, we have many drugs that fall under Orphan drug status. While those drugs might have a 340b price, we cannot take advantage of them. It sounds like you would still expect us to bill at the 340b price, whether we paid that or not. We already see Medicaid patients for less than cost, this would further compound the problem and would be an untenable position for us.

Lastly, the dispensing fee seems unreasonable. Data regarding the cost to dispense to Medicaid patient in Vermont shows the cost to be \$19.75, significantly more than the \$10.21 the State is proposing.

In conclusion, I would like to reiterate what I've heard multiple times from HRSA as we have explored the 340b option – 340b was designed to help the Safety Net Hospital system, of which we are a part, not to help the State Medicaid budgets. While we don't mind being a partner with the states, we do feel we already carry a significant portion of the care of the uninsured and need every penny we can to stay alive. In FY2009, we billed Vermont Medicaid \$683,973 in hospital outpatient charges, for a total cost of \$362,300. We were only paid \$157,187 – already a loss. This would increase that even further. In addition, in FY2010, we have written

off \$4.8 million in patient care due to lack of payment – we have been watching that rise over the past 4 years as the paper mills in our region all close. The last one, operating in Berlin, NH closed last week.

I feel very strongly that hospitals need to do all they can to control their costs – I’m sure you would agree. The 340b program will help us do that, but only if our payment is not penalized by doing so.

Bi-State Primary Care Association has a membership that includes both Federally Qualified Health Centers (FQHCs), which have been eligible entities for 340B, and Critical Access Hospitals who are newly eligible entities. All eight FQHCs in Vermont currently have 340B programs, although their internal structures and methods of administration can be quite different. Five FQHCs participate in a common Vermont pharmacy (Community Health Pharmacy) with a contracted administrator. The other three FQHCs have developed their own individual programs with variation in the cost and structure of their programs.

The state of Vermont has advocated for the expansion of the 340B program for many years, including a report on the program requested by the legislature to study potential opportunities for expansion in Vermont. It was determined in that report (2005) from OVHA that FQHC adoption of the 340B program and reductions available for medicine costs would have great financial benefits for patients and the state. It concluded that the “best vehicle for expansion of 340B in Vermont was expansion of FQHCs”. Subsequently, the legislature appropriated \$400,000 for the purposes of FQHC and 340B expansion.

After the report was published, and with new resources that became available, many activities have occurred that have resulted in a significant expansion of 340B participation by FQHCs. The number of FQHCs in Vermont has grown from five in 2005 to eight in 2010 and their participation in 340B has been supported by advocacy, education, grant support, and innovations in structure and dispensing of medicines by FQHCs. This has resulted in increased access to lower cost medicines for a growing number of patients in a broad geographical scope.

Community Health Pharmacy (CHRx) a Vermont organization that enabled a collaborative approach for prescription delivery by five FQHCs was formed in 2007, and has been operational since 2008. Other FQHCs outside of CHRx are also now operating 340B programs to provide 340B pharmacy benefits without the expense and risk of operating their own pharmacy. In some cases where pharmacy volume is low, this may actually be the only viable way to institute and viably sustain 340B pharmacy services.

The model of contracted relationships with community pharmacies may also have additional benefits for FQHCs, patients, and the state. By contracting with “several” pharmacies in their service area, the number of 340B access points is expanded and the number of eligible patients can increase. One FQHC projection for this model of delivery suggested a potential two to four fold volume increase would be possible with multi-pharmacy agreements. It is also important to consider that for FQHCs that have negotiated a “fill” fee with community pharmacies, a reduction in the dispensing fee would become a major challenge for the continuation or expansion of this model to increase access.

Additionally, it should be noted: that there has been significant cooperation between FQHCs and Designated Mental Health Agencies in Vermont to establish agreements that will enable individuals served by DAs to become eligible for 340B as patients of FQHCs. This is occurring with the strong support of the Department of Mental Health, DVHA, and the Challenges for Change statewide initiative that recommends behavioral health and primary care integration and unlike retail pharmacies the FQHC 340B pharmacy programs are mandated to provide discounted medicines to patients with little or no ability to pay.

Much of the progress to date and expected in the future has been predicated on the reimbursement formula that was negotiated with the state. As it was always the intention to reduce Rx product cost with 340B pricing it was determined that a higher dispensing fee would offset development and participation costs for FQHCs. This strategy has been successful based on the expansion of eligible entities and the increasing number of participating patients served by this program.

The participation of all eight FQHCs in 340B is very significant for this state given the number of sites (41), the primary care patient population (over 107,000) and the fact that they are located in underserved and for the most part rural locations. These numbers are expected to continue to grow with new FQHC approvals and expansions supported by federal resources.

To reduce the dispensing fee for FQHCs with 340B programs could have a significant negative economic impact on those programs that may jeopardize this continued participation and expansion. Basing a fee reduction on other state rates does not take into consideration the rural demographics of Vermont, the volume cost savings available in other states, geographical access to pharmacies in Vermont and the cost savings that are now occurring for patients and payers that the 340B initiative has achieved. Consideration must be given to the comparison of 340B Medicaid reimbursement and non-340B Medicaid reimbursement for prescriptions to ensure that a financial incentive remains for the utilization of the 340B program to maintain product cost savings.

We strongly suggest that the 340B dispensing fee reduction as proposed in the state plan amendment should be analyzed by DVHA to determine the potential impact on medicine costs, access and continued participation or expansion of 340B utilization that has been the state intent to date. We would also suggest that a study should examine other operational, policy, regulatory and state legal strategies or changes that could be proposed to enhance 340B utilization and reduce Medicaid pharmacy costs statewide. This would be a better basis for determination of an appropriate dispensing fee, and would be supported by our safety net providers to ensure that there is not an unintended negative impact adversely affecting their organizations, patients and state health costs.

We are a relatively small health center in eastern Vermont with 10 medical providers providing primary care out of three separate clinics. Although we receive federal grant money that subsidizes 14% of our operations, that barely covers the uncompensated care we provide and the extra overhead required for federal grant management and compliance. Our 340B program with two local contract pharmacies has been literally the key business strategy that has kept our doors open. Medicaid recipients represent 23% of our clientele, and generate more than 5000 prescriptions a year. It costs us \$21.50 on top of the cost of the drug in additional fees (\$16.50 dispense fee and \$5.00 PBM fee) for every script that goes through the 340B program, so we would lose \$11.30 per Medicaid script if Medicaid was carved in and reimbursed at the proposed \$10.20. This translates to a loss of least \$56,000 per year for us, as a very conservative estimate. We could not sustain a loss like that for long. I understand the fiscal challenges to keeping the Medicaid program sustainable, and I believe that SPA 10-011 is an honest attempt at a creative way of doing so, but it will not work in the long run if the community health centers lose money in the process. I urge you to continue the discussion but work toward a solution that is a win-win for all, not a significant loss for those of us who provide care to our most vulnerable citizens.

The Community Health Pharmacy (CHP) has been in operation since November 2008 and is currently filling approximately 416 Medicaid prescriptions per month at an enhanced dispense fee of \$14.25 per prescription. Medicaid prescriptions comprise approximately 16% of CHP's overall prescription volume. A dispense fee of \$10.20 would effectively reduce CHP's revenue by approximately \$20,218 per year. Although this is negligible savings to Medicaid, it is a significant reduction in revenue for a pharmacy, whose mission is to provide discounted medications to those with little or no ability to pay. A reduction such as this would have significant impact on CHP and jeopardize the financial viability of the entire operation. During the planning phases of the Community Health Pharmacy in 2008, project leaders worked closely with Vermont Medicaid to establish a mutually beneficial relationship that would use 340B pricing to offset the state Medicaid spend, while also providing a dispensing fee sufficient to cover operating expenses of the central fill pharmacy. With the assistance of the Heinz Foundation, Medicaid claims were analyzed to assess what dispensing fee could be negotiated between both parties to accomplish this objective. Even with an enhanced dispensing fee of \$14.25, Medicaid savings were 13%. Community Health Pharmacy revisited this analysis in September 2010 to estimate the overall savings to the Medicaid program through CHP. Claims data from January 1, 2010 through July 31, 2010 was reviewed and priced at Medicaid's network reimbursement rate. In the absence of Medicaid

rebate data for 2010, several different methodologies were utilized to estimate Medicaid's rebate (see Scenarios 1-4). The savings to Medicaid were still significant, despite the \$14.25 dispense fee. Even the most conservative savings estimate was over \$36,000 a year or 22%, therefore illustrating that the 2008 analysis was still valid. These figures are included with this letter and CHP would welcome a more in-depth analysis, with the cooperation of Medicaid by providing its average rebate amount per claim. With the changes in Health Care reform and the subsequent lowering of 340B prices, the estimated savings to Medicaid will only increase over the ensuing months and years, however, the Department has seized this opportunity to reduce reimbursement to 340B pharmacies. Unlike typical retail pharmacies, 340B pharmacies have a mandate to provide discounted pharmaceuticals to patients with little or no ability to pay. Prescriptions filled for Medicaid and Medicare represent the pharmacies only source of revenue and even so, the profit is marginal at best. CHP's average cost to dispense is greater than \$14.25, so it is currently losing money on every prescription filled on Medicaid. To reduce the reimbursement even further will make the prospect of filling Medicaid prescriptions a bleak prospect. CHP will have no choice but to "carve out" Medicaid prescriptions and utilize a separate inventory. Under this model, CHP would profit significantly, while Medicaid would lose its current savings. In addition to the points above, CHP rejects the Department's claim that the average cost to dispense is \$10.20 in Vermont. The cost to dispense is actually much higher. A 2007 report conducted by the Office of Vermont Health Access, entitled "Medicaid Generic Reimbursement Rate Reductions and Dispensing Fee Study" found that the average cost to dispense was actually \$10.55 per prescription. This was three years ago. Therefore, the claim that after three years of inflation, the cost to dispense has actually declined to \$10.20 is absurd. Excerpts from this report are also included as an appendix to this letter. More recent studies demonstrate that the average cost to dispense in the Northeast region is actually closer to \$12.83 per prescription. Included as an appendix to this letter is a 2009 national study conducted by Cardinal Health, which illustrates these figures on page 25. Furthermore, CHP rejects the notion that the Department should pay 340B pharmacies a dispense fee equal to its average cost to dispense, while reimbursing retail pharmacies at a profit margin. Even if the Department increased its reimbursement to match the current cost to dispense of \$12.83, this allows for no margin, which helps fund the expansion of services by the FQHCs. The average gross profit of a retail pharmacy is 23%, as reflected on page 7 of the Cardinal Health report. In essence, the Department is paying the national pharmacy chains at a profit of 23%, while discriminating against 340B participating pharmacies, which are owned by Vermont's already financially burdened Federally Qualified Health Centers, Critical Access Hospitals, and Community Health Centers, who have a mandate to subsidize care to the uninsured. In closing, Community Health Pharmacy strongly opposes the Department's proposal to reduce the dispensing fee from \$14.25 to \$10.20 per prescription. In fact, CHP recommends a 5% increase in the dispensing fee, to accommodate for inflation over the past two years since the rate was established.

	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Network dispense fees	\$ 13,794.00	\$ 13,794.00	\$ 13,794.00	\$ 13,794.00
Network Ingredient Cost	\$291,465.12	\$291,465.12	\$291,465.12	\$291,465.12
Total Network Price	\$305,259.12	\$305,259.12	\$305,259.12	\$305,259.12
Medicaid rebate estimate*	\$ 56,833.36	\$ 14,776.84	\$126,410.79	\$ 80,051.93
Medicaid Net Rebate Price	\$248,425.75	\$290,482.28	\$165,054.32	\$225,207.19
CHP Price	\$143,763.44	\$143,763.44	\$143,763.44	\$143,763.44
Savings Annualized	\$179,421.11	\$251,518.01	\$ 36,498.66	\$139,617.86
Medicaid Net Rebate Price per Rx	\$ 85.40	\$ 99.86	\$ 56.74	\$ 77.42
CHP Price per Rx	\$ 49.42	\$ 49.42	\$ 49.42	\$ 49.42
Savings per Rx	\$ 35.95	\$ 50.44	\$ 7.32	\$ 28.00

*In the absence of rebate data, the Medicaid rebate has been estimated based on a range of scenarios below:

Scenario 1: Assume AMP is 80% of AWP and the Medicaid rebate is 15.1% of AMP for brands and 11.1% for generics (source: SNPHA 2007)

Scenario 2: Assume Medicaid rebate net price is 51% of AWP (source: Congressional Budget Office, 2007)

Scenario 3: Assume Medicaid net price is 11.5% of AWP more than 340B (source: Jimmy Mitchell, HRSA Director of OPA, 2007)

Scenario 4: Assume Medicaid rebate is \$0.2427 per unit (source: FQ 4 2007 Vermont Medicaid rebate data)

Additional Comments:

First of all, it seems problematic to me that Vermont Medicaid can "cherry pick" the reimbursement they will pay 340B providers based on a *lesser than* formula of 340B acquisition cost + 340B dispensing fee; or AWP-14.2% + standard in-state (non-340B) dispensing fee. If Medicaid is carved in to 340B, then the reimbursement must be 340B acquisition + a negotiated fill fee. They cannot pay a discount off AWP, which could result in a margin being made on the drug cost. This leads to the possibility of double-dipping, which is a Federal rule.

Secondly, it sounds as though the intent is to force all 340B providers to "carve in" Medicaid, regardless of the covered entity's preference. I am not sure if this is the intent, however, this seems problematic too and I don't understand how the state can mandate this. It's ultimately up to the 340B covered entities whether they want to carve in or carve out Medicaid, based on their unique business rules and financial considerations. Now, if Medicaid provides a healthy dispense fee on carving in, then obviously that would incentivize many 340B providers to pursue that route instead of carving out. But I'm not sure they can really mandate it.

I am writing this in response to DVHA's proposal for the enhanced Safety Net dispensing fee for 340b covered entities. The main issue that I see with this plan is that it presupposes that the pharmacies involved in the dispensing of 340b product are solely 340b pharmacies. Contracted pharmacies, like us, provide both 340b and regular retail pharmacy services to our community and it is here that a major issue exists.

Let me begin by explaining that in a contractual arraignment like ours, we have no knowledge of which dispenses are 340b eligible and which are not, at the point of sale. Eligibility is determined after the fact and most often by a third party, in our case by Mr. Donnelly and his team at Hudson Headwaters Health Network. If the DVHA and MedMetrics were to require transmission of 340b acquisition cost at the point of the claim submission then the contracted pharmacy would have to be able to identify 340b eligible prescriptions from regular retail prescriptions. Let me simply say that this would be very difficult. This would also require the contracted pharmacy to have duplicate sets of data for each NDC number available under the program. This possesses varying degrees of difficulty depending on the pharmacy software involved.

I believe that the state will have a hard time finding willing entities if it cannot answer some of these "how to" questions.

Presumably, all auditing and separation of 340b from regular retail would have to occur at the pharmacy level and thereby, an expense that they and the entity would have to incur. If that holds true then \$10.20 above acquisition cost would not be an adequate fee schedule. There is no question that the 340b program offers a great means of savings. I would hate to see this opportunity lost because it failed in practical application.

I am replying to your e-mail requesting comment on the Vermont Medicaid 340B Implementation. We are hopeful that we can get an agreement, so that we can access 340B pricing to save money and provide care for those that are in need. There are concerns that with the limited amount of information available, we are not sure how open ended an agreement we are signing. As I am sure you are aware hospital budgets are not budgeted with a surplus and we are all struggling to keep serving the population in our service areas.

One of my first concerns for Critical Access Hospitals like ours, would be if we carve in Medicaid, what will this mean for the outpatients served by our hospital in the Clinics, Emergency Department and the Operating room, radiology outpatients. Last quarter 68% of dollars used were outpatients at the hospital. I am not sure how the drugs used for Medicaid patients would be reimbursed. Is this covered by a dispensing fee of \$10.20 whether a \$3000 chemo in the outpatient clinic or a \$5.00 IV antibiotic in the ED. Currently our billing office tells me we do report NDC numbers to the state Medicaid which they may use to get a Medicaid rebate on all specialty (636) drugs. Separation of outpatient drugs from inpatient in many cases will require either separate

inventory with 340B or adequate data mining to show no diversion is taking place of drugs intended for outpatients if drugs are managed on a replacement basis. We may be limited to certain drugs to keep this clean and auditable. It will be some months before we can capture much of the potential savings. Had the bill not been changed at the last minute to be for outpatient only, then the process for CAH's the would have been much simpler.

For prescriptions filled at the retail pharmacy level, with the **One to Many Model** that was just allowed it is too costly to maintain a 2nd inventory in multiple pharmacies, so a replenishment model is more likely to be selected, as with the SMCS Program. These pharmacies, which we work with are paid a dispensing fee by the 340B entity for **Brand Drugs and other drugs on formulary**. We also pay processing fees. \$10.20 currently will not cover that cost. This places a burden on the 340B entity. Many generic drugs do not produce a break even when you deduct the processing fee and the dispensing fee to the pharmacy. We also fully pay for prescriptions for a population in need by certain criteria.

When you refer to the 340B entity, I assume you mean the Critical Access Hospital and Sole Community Hospital or other entity rather than the dispensing (by contract) pharmacy. With the State approving our hospital budgets, I doubt we will ever open our own pharmacy, but more likely contract with those interested. We have been doing this for close to 4 months now in Springfield and Bellows Falls with the help of Hudson Headwater in New York. I have to give credit to the two Pharmacies that are working with us. Patients may not be identified at point of sale as being 340B eligible with our program in addition to being Medicaid. We are still learning and reversing after 4 months time prescriptions which we filled under the 340B program and for one reason or another had to reverse. The complications of adding the Medicaid carve in, on top of everything else may be too much for some pharmacies further limiting access to 340B pricing for those and others. This program is through the FQHC and the hospital specialist will eventually be referral Physician under this system. In order to get this done I will carve out Medicaid until such time as we switch the FQHC. This can be easily changed with HRSA if we can figure out mechanisms that work.

The draft amendment to the medicaid provider agreement in time looks good. Hopefully we can get an agreement in place for the 9/27 deadline rather than loose 3 months.

We are responding to your e-mail requesting input with regard to the Vermont Medicaid 340B Implementation. With the importance of the 340B program and the patients it will serve in our community, we are hopeful that all concerns can be addressed to continue to offer this much needed program and possibly expand to offer the service to even more patients.

As with many other pharmacies, we rely on an outside source to handle the task of determining which dispenses are 340B eligible and then reporting that information back to us. Under the system proposed for the Medicaid piece much of this task would be put on the pharmacy and its staff which would not necessarily have the appropriate knowledge to make such decisions. This is a challenging task when you are processing both retail prescriptions and 340B prescriptions. From our perspective this would be very difficult to accomplish and leads us to have many questions at the onset. Additionally, the task of maintaining two inventories in order to achieve the needed transmission of these prescriptions raises many more questions and concerns, and as it is proposed is a very labor intensive process. With your proposed method of including Medicaid it appears to us that much of the responsibility of the program for processing of these claims moves to the pharmacy rather than the coordinating entity for the program, thereby causing more issues to arise and possibly more opportunity for errors.

Without more information on the specifics of including these transmissions, it is difficult to determine how feasible it would be for us as a participating pharmacy to continue to participate should Medicaid get worked into the program. With more responsibility being placed onto the pharmacy for these transmissions and other factors involved, we do not feel that \$10.20 above acquisition is an appropriate fee schedule as proposed. For all drugs currently dispensed under the Medicaid program our average margin is between \$15 -\$18 so why

would we considering doing it for less with an increased work load. We expect a higher fee given the Medicaid 340B program would require increased labor and intense training of pharmacy staff.

While we feel this program is beneficial in many ways, we would need more specific information and reimbursement concerns addressed before seeing Medicaid get included into the 340B program.

Bi-State Primary Care Association has a membership that includes both Federally Qualified Health Centers (FQHCs), which have been eligible entities for 340B, and Critical Access Hospitals who are newly eligible entities. All eight FQHCs in Vermont currently have 340B programs, although their internal structures and methods of administration can be quite different. Five FQHCs participate in a common Vermont pharmacy (Community Health Pharmacy) with a contracted administrator. The other three FQHCs have developed their own individual programs with variability in the cost and structure of their programs.

The state of Vermont has advocated for the expansion of the 340B program for many years, including a report on the program requested by the legislature to study potential opportunities for expansion in Vermont. It was determined in that report (2005) from OVHA that FQHC adoption of the 340B program and reductions available for medicine costs would have great financial benefits for patients and the state. It concluded that the “best vehicle for expansion of 340B in Vermont was expansion of FQHCs”. Subsequently, the legislature appropriated \$400,000 for the purposes of FQHC and 340B expansion.

After the report was published, and with new resources that became available, many activities have occurred that have resulted in a significant expansion of 340B participation by FQHCs. The number of FQHCs in Vermont has grown from five in 2005 to eight in 2010 and their participation in 340B has been supported by advocacy, education, grant support, and innovations in structure and dispensing of medicines by FQHCs. This has resulted in increased access to lower cost medicines for a growing number of patients with a broad geographical scope.

Community Health Pharmacy (CHRx) a Vermont organization that enabled a collaborative approach for prescription delivery by five FQHCs was formed in 2007, and has been operational since 2008. Other FQHCs outside of CHRx are now operating 340B programs where they provide 340B pharmacy benefits without the expense and risk of operating their own pharmacy. In some cases where pharmacy volume is low, this may actually be the only viable way to institute and viably sustain 340B pharmacy services. The model of contracted relationships with community pharmacies may also have additional benefits for FQHCs, patients, and the state. By contracting with “several” pharmacies in their service area, the number of 340B access points is expanded and the number of eligible patients can increase. One FQHC projection for this model of delivery suggested a potential two to four fold volume increase would be possible with multi-pharmacy agreements. It is also important to consider that for FQHCs that have negotiated a “fill” fee with community pharmacies, a reduction in the dispensing fee would become a major challenge for the continuation or expansion of this model to increase access.

Additionally, it should be noted that there has been significant cooperation between FQHCs and Designated Agencies (DA) in Vermont to establish agreements that will enable individuals served by DAs to become eligible for 340B as patients of FQHCs. This is occurring with the strong support of the Department of Mental Health, DVHA, and the Challenges for Change statewide initiative that recommends behavioral health and primary care integration.

Much of the progress to date and expected in the future has been predicated on the reimbursement formula that was negotiated with the state. As it was always the intention to reduce Rx product cost with 340B pricing it was determined that a higher dispensing fee would offset development and participation costs for FQHCs. This strategy has been successful based on the expansion of eligible entities and participating patients that has occurred.

The participation of all eight FQHCs in 340B is very significant for this state given the number of sites (41), the primary care patient population (over 107,000) and the fact that they are located in underserved and for the most part rural locations. These numbers are expected to continue to grow with new FQHC approvals and expansions supported by federal resources.

To reduce the dispensing fee for FQHCs with 340B programs could have a significant negative economic impact on those programs that may jeopardize this continued participation and expansion. Basing a fee reduction on other state rates does not take into consideration the rural demographics of Vermont, the volume cost savings available in other states, geographical access to pharmacies in Vermont and the cost savings that are now occurring for patients and payers that the 340B initiative has achieved. Also, consideration must be given to the comparison of 340B Medicaid reimbursement and non-340B Medicaid reimbursement for prescriptions to ensure that a financial incentive remains for the utilization of the 340B program to maintain product cost savings.

We strongly suggest that before any dispensing fee is changed for FQHCs, that a complete analysis should occur to determine the potential impact on medicine costs, access and continued participation or expansion, as has been the intent to date. This could be a better basis for a determining an appropriate dispensing fee, and would be appreciated by our safety net providers to ensure that there is not an unintended negative impact adversely affecting their organizations and patients.

I would like to illustrate that there is a very clear difference between the types of pharmaceuticals dispensed in the retail segment versus the institutional segment. Therefore a "one size fits all" dispensing fee is not equitable. It is not clear if the dispensing fee that you have proposed is intended for retail pharmacy claim submission, or all 340B eligible pharmaceuticals dispensed to Medicaid patients.

On the outpatient retail side, the new dispensing fee would add about \$90,000 in revenue from dispensing fees per year compared to the current fee of \$4.75, but the proposed fee is below our actual average dispensing cost of \$12.50 per prescription (which does not include any overhead costs).

On the institutional outpatient side, after reviewing the type of pharmaceuticals that we are currently being reimbursed for, our calculated dispensing costs for these products range from \$19.00 to \$67.00 per dose, with many – like chemotherapy – falling at the top end of the range.

As a result of the (federal) Deficit Reduction Act of 2006, the Vermont Community Retail Pharmacy Coalition (VCRPC) engaged with legislative committees of jurisdiction and OVHA to respond to evolving federal prescription drug policy. VCRPC proposed a Vermont cost of dispensing study rather than relying on national dispensing fee studies. OVHA engaged the University of Connecticut School of Pharmacy to undertake such a study. The report "Medicaid Generic Reduction and Dispensing Fee Study" (January 2007) established the Vermont average dispensing fee at \$10.55.

Three years have passed. Community retail pharmacy believes its cost of dispensing has increased, not declined.

DVHA has not revealed, in the documents posted on its Website, any justification for establishment of a \$10.20 dispensing fee for 340B prescriptions below the cost of dispensing, and therefore it should be withdrawn.

Vermont's community retail pharmacies have other questions and concerns about the 340B expansion, but reserves those for a later time given these comments are directed only to this proposed State Plan Amendment.

We have several serious concerns about the Draft SPA, both in regard to procedure and substance. First and foremost, we strongly object to the Draft SPA having an effective date of October 1, 2010, one week after its initial public announcement and one week prior to a revised public announcement. The October 1 effective date is also nearly three weeks prior to the Wednesday, October 20, deadline for comments, and almost four weeks before the public hearing scheduled for October 25. Meaningful public input is a critical legal requirement for

rulemaking and implementation of state plan amendments. If adopted, the proposed changes represent the need for significant technical and operational planning for Fletcher Allen Health Care, the only currently participating 340B hospital in the state. We therefore request that DVHA amend the effective date to allow an adequate lead time to fully assess the impact and implications of the change. Our second related procedural concern is that DVHA has not provided any fiscal analysis in support of the Draft SPA. To the extent that 340B-participating hospitals are required to pass through acquisition costs, our understanding is that DVHA will not be eligible to claim manufacturers' rebates on those pharmaceuticals. It is unclear to us what the fiscal impact this trade-off represents. We also believe a fiscal impact analysis is warranted on the costs to comply and the lost revenue that would be absorbed by affected entities, and the implications of that impact. Our initial estimates indicate a combined impact to Fletcher Allen of at least \$800,000 annually between lost reimbursement for pharmaceuticals and the operational costs to ensure our inventory and billing systems are minimally ready to calculate the 340B volume and cost for Medicaid patients. Given the very recent publication of the Draft SPA, this financial impact is not incorporated in our Fiscal Year 2011 BISHCA budget order from mid-September. Combined with a major unexpected decrease in our Disproportionate Share (DSH) revenue from DVHA, another unbudgeted and recent change, we are taking steps to reopen our budget order with BISHCA to ensure we can replace this lost margin.

As a strong central concern with the Draft SPA and Technical Specifications, Fletcher Allen is not currently equipped through either a software or process solution to comply with the billing instructions outlined. It is not clear that our systems can comply with the Draft SPA and Technical Specifications as currently written without substantial technology investment and/or a large increase in manual processes. We are assessing when and if there is a reasonable and accurate way to comply, and if so what effort, expense, and lead time will be required. We have learned from our colleagues and trade associations that there is no easily-implemented method or software solution for the approach required by the Draft SPA. In fact, many providers simply cannot comply with a Medicaid directive to pass through 340B pricing on a claim-by-claim basis. We would need to alter the gross charge generation method for just Medicaid claims to comply with the Technical Specifications. This is contrary to the architecture and policy of our charging and billing systems, and may require us to build and maintain a full shadow-system, including custom programming, to replace the standardized, single charge description master ("Charge Master") gross charge calculation process. It would also require a 340B cost data source integrated in our charging and billing systems in lieu of our Charge Master, again only for Medicaid claims. Such a database table does not exist in our billing systems, nor does a method to accurately match purchased pharmaceutical invoices with specific patient encounters. 340B pricing can and does change even for the same drug, and in unpredictable patterns. Again, given the very recent release of the Technical Specifications, we have not fully assessed the requirements or implications of these specifications on our systems, let alone designed a solution. We will need adequate time to generate the most feasible way to accurately meet the requirements, assuming this is possible, and without the addition of a labor-intensive, costly maintenance process or manual entry of charges on Medicaid claims. We also have concerns about the Draft SPA from a policy perspective. The Draft SPA indicates that Medicaid intends to pay the lesser of 340B cost or the currently in-force methods for the Medicaid drug fee schedules. We believe that 340B entities should not be subject to the "lesser of" provision. We have generally understood 340B to be a program to afford safety net hospitals lower pharmaceutical costs and the ability to stretch scarce resources to serve under- and uninsured patients. At the same time, we recognize CMS's desire that Medicaid programs obtain optimal drug pricing from manufacturers. Balancing these interests, we do not perceive that Medicaid agencies should require 340B pass through pricing, but if they do, there certainly is no intention for them to take more than the total 340B benefit as applied to Medicaid patients. To clarify, our position is that a Medicaid program's right to 340B pass-through pricing may require the Medicaid program to *always* pay the 340B cost and not below that for selected drugs or situations.

Additionally, we understand that the dispensing fee for retail prescriptions filled at Medicaid enrolled pharmacies will increase from \$4.75 to \$10.20. This increased amount still does not cover the actual dispensing costs in the Fletcher Allen retail pharmacy, and as such does not represent an adequate level of payment.

Combined with the "lesser of" method likely paying us below acquisition cost in some or perhaps many instances, we have significant concerns about the overall fiscal impact of the Draft SPA.

We also interpret the Draft SPA, as it applies to outpatient services, to leave in place existing drug administration reimbursement at current levels. We believe that reimbursement for these drug administration codes, where applicable, also does not cover the actual operational costs of drug administration in our outpatient service settings.

We are currently holding outpatient claims to Vermont Medicaid that include reimbursable J – code drugs for which we are already participating in the 340B program. We have been holding claims for dates of service after October 1, 2010, the effective date indicated in the Draft SPA, and these claims currently represent over \$800,000 in total charges. We will not be able to continue this practice indefinitely and absorb the material reimbursement delay it represents. We therefore request DVHA to implement one or more of the following actions: (i) publish substantive changes to the Draft SPA and Technical Specifications such that that they no longer require changes to provider billing practices; (ii) change the Draft SPA to include a future effective date; or (iii) grant Fletcher Allen a waiver of the requirements of the Draft SPA for a defined and adequate time period as the only currently participating 340B hospital in Vermont.

Thank you for the opportunity to respond to the proposal to set a dispensing fee for Medicaid prescriptions that are carved into 340B program. The NOTCH Pharmacy has not had the time to review the impact on the Pharmacy but on the surface it appears that there would be a reduction of income for the NOTCH Pharmacy. I also think that a fill fee of \$10.20 would be too low to convince contract pharmacies to participate in the 340B program.

Questions we will need to have answered so we could continue to review the proposal are is this for only Primary Medicaid is the dispensing fee for Brands and Generic fills and how are you going to determine acquisition cost?

340B Inventory Management and Preventing Diversion



Learning Objectives

1
Review
different
options for
implementing
340B

2
Discuss 340B
requirements

3
Understand
the GPO
exclusion and
why it is
important

4
Understand
key elements
of
implementing
340B split-bill

5
Understand
virtual
inventory
workflow

INTEGRITY ? ACCESS ? VALUE

2

Hospital Inventory at a Glance

- Most medication distributed to med areas/automated dispensing cabinets from one central stock
- Satellite areas may exist that order and receive their own medications
- Medications charged by a generic charge code that could represent multiple NDC's



INTEGRITY ? ACCESS ? VALUE

3

Study re Medicaid

Pre-rebate Medicaid to 340B comparison

Implementation and on-going administration costs

Savings vary by program

Managed Medicaid plan

Post-rebate to 340B comparison

Areas of Opportunity For Hospitals

- Satellite outpatient areas (i.e. retail, infusion center)
- Outpatient-only areas supplied from inpatient stock
 - outpatient clinics
 - day surgery
- Mixed-use settings
 - emergency room
 - operating room



INTEGRITY ? ACCESS ? VALUE

- Outpatient areas that only see qualified patients and that order, stock, and receive their own segregated supply may begin to purchase immediately under an outpatient account with wholesaler (i.e. “satellites” from previous slide)
- “Mixed” areas and other outpatient areas will need to implement an inventory tracking system to ensure appropriate program integrity and prevent 340B diversion

Implementation Models

- physical inventory separation
 - pharmacy will purchase and stock 340B eligible, 340B, 340B non-eligible, and GPO inventories
 - not advisable unless facility inventory is very low
- virtual replenishment model

INTEGRITY ? ACCESS ? VALUE

Visualizing Split Billing

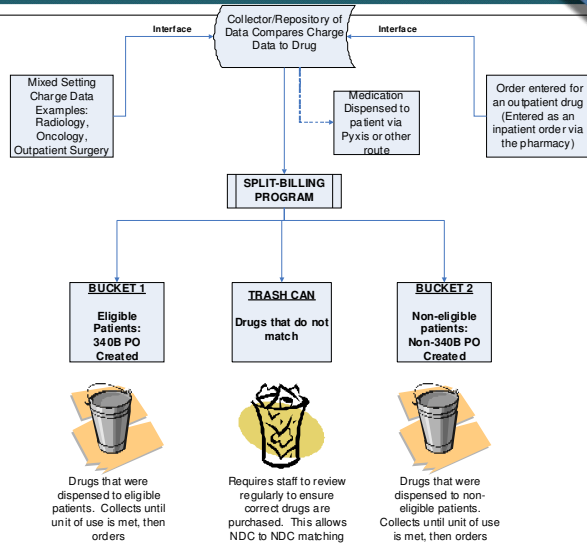
General Concept

- No two programs are the exact same
- Orders placed into 'buckets'
- Wholesaler dependent or independent
- Manual or software
- Companies change payment strategies often
- Requires buyer/inventory personnel to be engaged in the ordering process

INTEGRITY ? ACCESS ? VALUE

See handout; get from PVP website-

Virtual Inventory Concept



INTEGRITY ? ACCESS ? VALUE

7

Study re Medicaid

Pre-rebate Medicaid to 340B comparison

Implementation and on-going administration costs

Savings vary by program

Managed Medicaid plan

Post-rebate to 340B comparison

Requirements

- Drugs must be administered to QUALIFIED 340B Patients
- Covered Entities must adhere to the GPO Exclusion
- Drugs must be replenished on an NDC-NDC basis
- Medicaid guidelines must be followed (carve-in vs. carve-out)
- Auditable records and reports must be maintained



INTEGRITY ? ACCESS ? VALUE 8

Study re Medicaid

Pre-rebate Medicaid to 340B comparison

Implementation and on-going administration costs

Savings vary by program

Managed Medicaid plan

Post-rebate to 340B comparison

Approaches to Split Billing

Manual "Home Grown"

- Utilization of excel data base to capture eligible outpatient transactions
- Patient identifier to show eligible outpatient visit, linked to dispensing of outpatient drug
- Order placed based on unit of purchase and replenished when unit of purchase met
- Inventory personnel must ensure NDC purchase matches original NDC dispensed
- Purchases based on trends

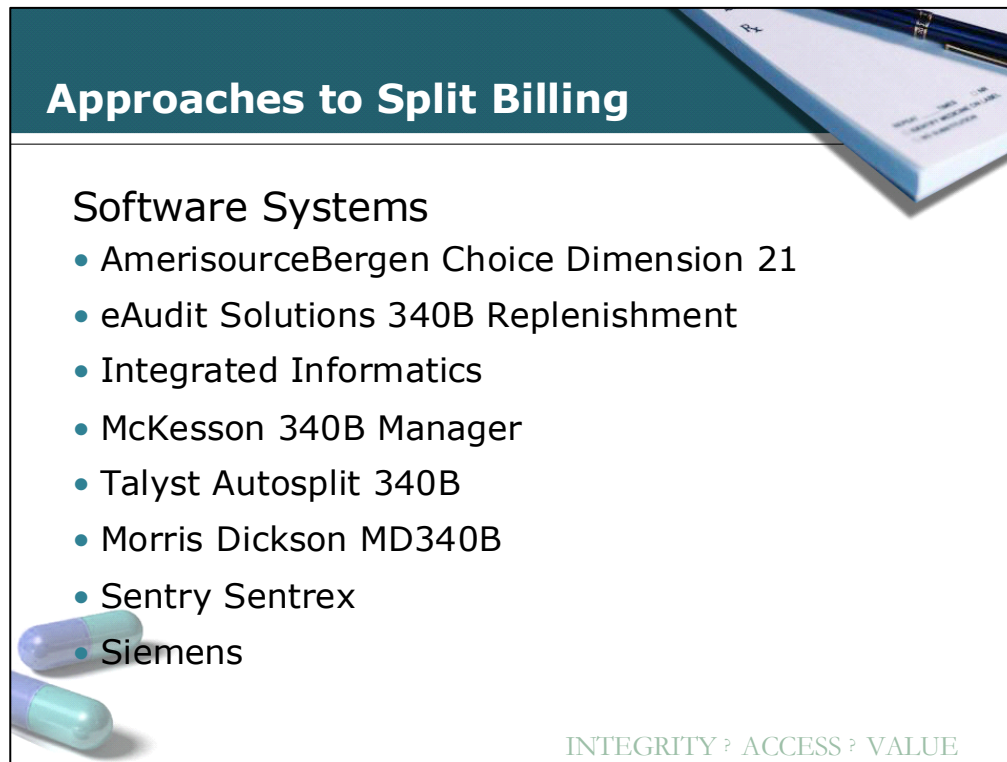


INTEGRITY ? ACCESS ? VALUE

Most common methodology; software is fairly new- – approx. 70% utilize this method/approx. 16% utilize this method

By show of hands how many utilize this methodology...

Requires CDM file to be monitored and cross walks built



Approaches to Split Billing

Software Systems

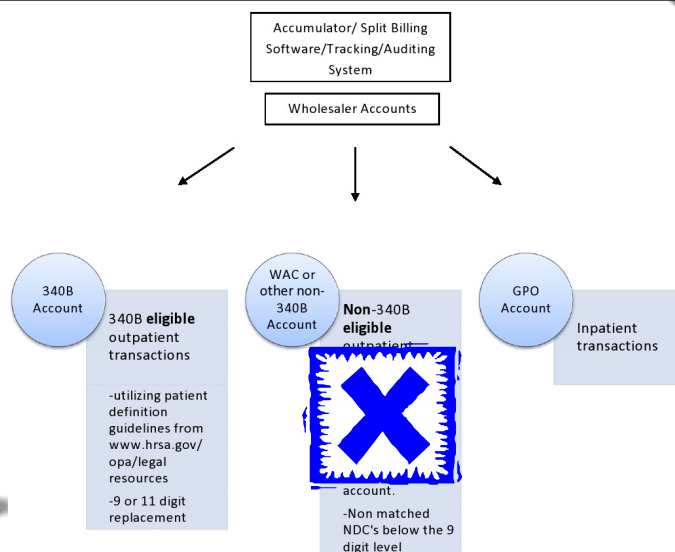
- AmerisourceBergen Choice Dimension 21
- eAudit Solutions 340B Replenishment
- Integrated Informatics
- McKesson 340B Manager
- Talyst Autosplit 340B
- Morris Dickson MD340B
- Sentry Sentrex
- Siemens

INTEGRITY ? ACCESS ? VALUE

Current software programs available; Talyst was formerly integrated healthcare systems
AmerisourceBergen- Automated-Choice; web version; dimension 21 total package
8% utilize this method (fairly new approach)

How many utilize software systems?....How many are considering the purchase of a software system?...

Wholesaler Account Setup



INTEGRITY ? ACCESS ? VALUE

Split-Billing Implementation

- Wholesaler configuration
 - level of detail will depend on amount of integration with wholesaler ordering platform
 - account set-up
 - purchase file (3rd party implementation)
 - EDI and PO import/export setup (3rd party implementation)
- Data set-up
 - determine number of accumulators
 - usage file
 - CDM crosswalk file
- Software Set-up and install
- Maintenance

INTEGRITY ? ACCESS ? VALUE

Usage File

- The accumulator is populated from charge data exported from hospital billing system
- Recommended to use a global, automated file imported daily
- Software will typically require a daily extract of charge/utilization data in a simple file format consisting of:
 - Charge code or NDC
 - Drug name, strength, and form
 - Charge quantity (note that this is not a package quantity)
 - Usage location (or specified accumulator)
 - Patient classification
- Pay careful attention to EC usage data

INTEGRITY ? ACCESS ? VALUE

Usage File Example

00003218710|ABATACEPT 250 MG IV SOLUTION|935.00|B|O

Charge code

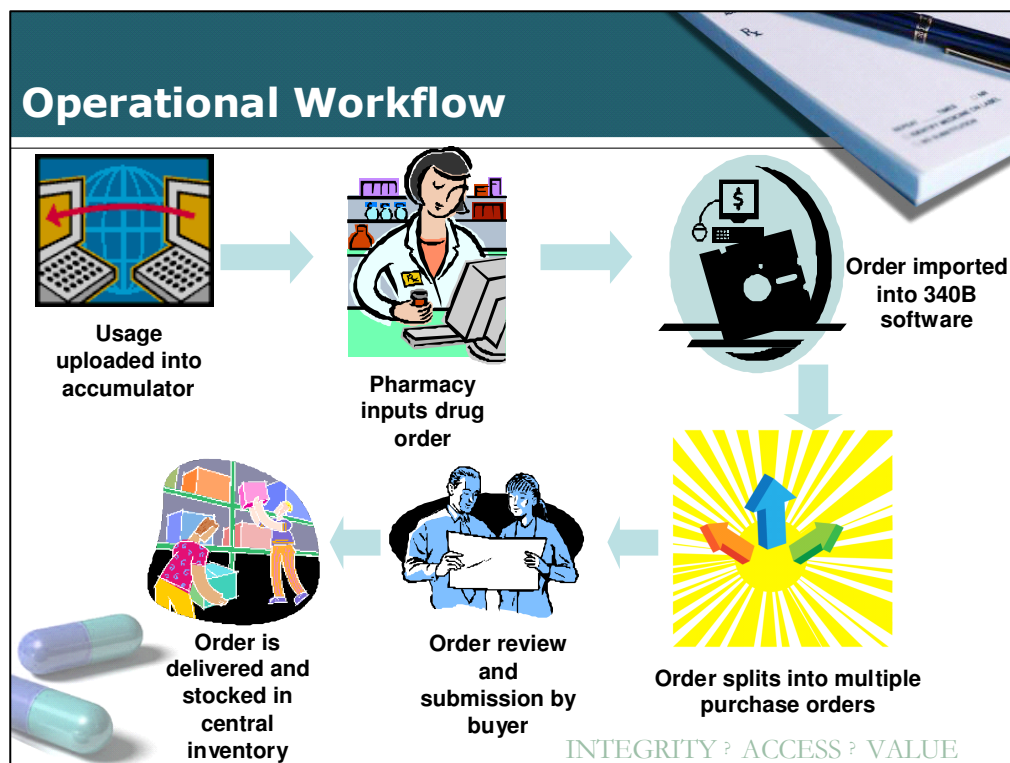
Drug Name
(optional)

Charge Qty

Location

Pt. Class

INTEGRITY ? ACCESS ? VALUE

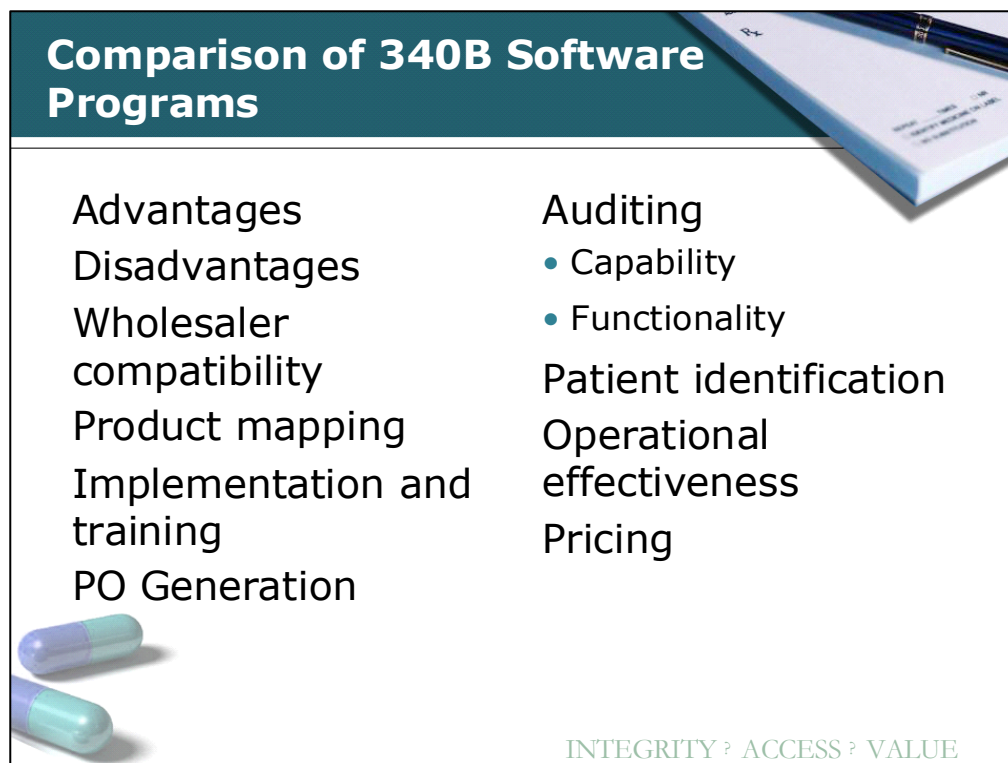


Many do not take advantage of 340B savings in these areas- resulting in non-compliance in the 340B program. Some may be more familiar with the terminology 'cherry picking'- not realizing that by not looking at all areas in the hospital setting you are essentially non-compliant-although your intentions are not bad.

Areas for opportunity...

i.e. Emergency center, urgent care, radiology, oncology, day surgery, recovery, observation, cardiology procedures, special procedures

Some systems have even taken into account DRG coding with therapeutic class of drugs



Comparison of 340B Software Programs

Advantages	Auditing
Disadvantages	• Capability
Wholesaler compatibility	• Functionality
Product mapping	Patient identification
Implementation and training	Operational effectiveness
PO Generation	Pricing

INTEGRITY ? ACCESS ? VALUE

Handout available for attendees.

Important to note that each individual reviewing the comparison spreadsheet will utilize it differently based on their individual hospitals circumstance. The categories on this slide show some of the major points that are reviewed for a hospital going through an RFP process to assist in the comparison. You may find that after reviewing the RFP process with your IT staff that other criteria may come into play as it relates to staffing resources.

It is important to know that these systems will allow you to pick drugs to purchase on 340B that you did not purchase on your inpatient GPO account. These overrides should be reviewed for appropriateness to ensure compliance. Many of the software programs have the capability to run reports for management to review. As part of utilizing the 340B program it is important that inventory personnel understand the program and that formularies are reviewed from both the inpatient and outpatient perspective to ensure the best selection of product (for price and therapeutic effect). There may be instances where the 340B price is higher than the GPO price, but this is not the norm. This also doesn't mean that on that particular drug you purchase only on the GPO account...this would be considered 'cherry picking'.

Comparison of 340B Software Programs-Continued

Recommendation/Conclusion

- Site specific
- Volume of transactions
- Wholesaler affiliation
- Contract/Agreement
 - Business Associate agreement
 - Prime Vendor Program www.340bpvp.com
 - See suppliers
 - Split billing
 - Comparison Tool

INTEGRITY ? ACCESS ? VALUE

specific-one software is not *the Best* software for any pharmacy
how real are the savings compared to the expense?
\$15 dollars for every \$1 spent

Important to note that each individual reviewing the comparison spreadsheet will utilize it differently based on their individual hospitals circumstance. The categories on this slide show some of the major points that are reviewed for a hospital going through an RFP process to assist in the comparison. You may find that after reviewing the RFP process with your IT staff that other criteria may come into play as it relates to staffing resources.

Challenges of Split-Billing

- Access to hospital billing system
- Identification of outpatient patients
- 340B formulary review for best price
- Backorders and Shortages
- Identification of outpatient mixed sitting areas from the Medicare cost report

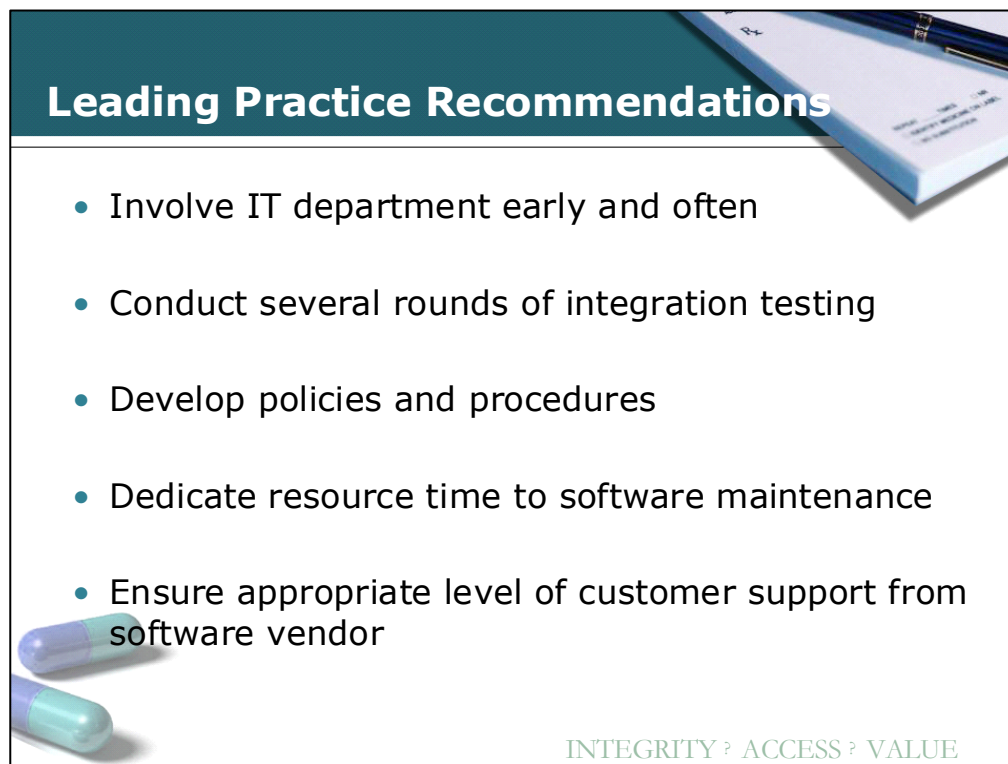
INTEGRITY ? ACCESS ? VALUE

Working with IT; how does it align with the priorities of the health system (if you can prepare in advance savings associated with implementing split billing- this wins IT and Finance) Beware- they may reduce your drug budget

Once accessing the billing system...the identification of outpatients vs inpatients can be challenging

It is important to know that these systems will allow you to pick drugs to purchase on 340B that you did not purchase on your inpatient GPO account. These overrides should be reviewed for appropriateness to ensure compliance. Many of the software programs have the capability to run reports for management to review. As part of utilizing the 340B program it is important that inventory personnel understand the program and that formularies are reviewed from both the inpatient and outpatient perspective to ensure the best selection of product (for price and therapeutic effect). There may be instances where the 340B price is higher than the GPO price, but this is not the norm. This also doesn't mean that on that particular drug you purchase only on the GPO account...this would be considered 'cherry picking'. ∅

Split billing implementation is not just a pharmacy project...it can save the health system as a whole; it's a win win...and will keep the organization compliant. As a former director of pharmacy- I know you like to sleep at night. There are plenty of other things to keep you awake...don't let 340B be one of them.



Leading Practice Recommendations

- Involve IT department early and often
- Conduct several rounds of integration testing
- Develop policies and procedures
- Dedicate resource time to software maintenance
- Ensure appropriate level of customer support from software vendor

INTEGRITY ? ACCESS ? VALUE

Resources to help entities optimize participation and use of the 340B are readily available. These services are FREE of charge and we encourage you to stop by the 340B Resource Center Booth to visit with our staff.

The first step is to visit the Office of Pharmacy Affairs website, at www.hrsa.gov/opa. This web site contains guidelines, enrollment forms, and access to other 340B information.

The second step is to contact PSSC. The PSSC call center operates from 9:00 a.m. to 4:30 p.m. eastern standard time at 1-800-628-6297, or email questions anytime to PSSC@aphanet.org.

Finally, detailed information about the Prime Vendor Program is available at www.340bpvp.com, or by calling 1-888-340-2787.

Two public meetings are scheduled. The first public meeting will be held on October 25, 2010 from 1 p.m. to 3 p.m. at the Department of Vermont Health Access, 312 Hurricane Lane, Williston, Vermont. The second meeting will be held on November 17, 2010 from 10 a.m. to 11:30 a.m. at the Department of Vermont Health Access, 312 Williston Vermont.

To get more information about 340B State Plan Amendment go to <http://dvha.vermont.gov/administration/draft-versions-of-state-plan-changes>.